

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

MDL No. 2419  
Master Dkt. 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

*Marko v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-10404;  
*Pennington v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10406;  
*Leaverton v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-10408;  
*Tolotti v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-10413;  
*Zavacki v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-10441;  
*Letizia v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-10442;  
*Tisa v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-10446;  
*Devilli v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-11167;  
*Effendian v. New England Compounding Pharmacy, Inc., et al.*  
Docket No. 13-cv-11233; and  
*Guzman v. v. New England Compounding Pharmacy, Inc., et al.* Docket No. 12-cv-12208

Leave to file Sur-Reply Granted by  
Judge Zobel on April 10, 2014 at Status  
Conference

**PLAINTIFFS' STEERING COMMITTEE'S SUR-REPLY MEMORANDUM IN  
OPPOSITION TO PREMIER DEFENDANTS' 12(b)(6) MOTION TO DISMISS**

The Master Complaint sets forth, in a detailed manner, sufficient facts to support each and every one of Plaintiffs' claims against the Premier Defendants. Nevertheless, with respect to Plaintiff's claim for civil conspiracy, the Premier Defendants' argue in their Reply brief that there is no evidence that NECC conspired with the Premier Defendants to, as is alleged in the Master Complaint, fraudulently violate Massachusetts' controlled substances and pharmacy practice statutes and regulations. (*See Defendants' Reply at 5 et seq.*). The Premier Defendants further contend in their Reply that Plaintiffs do not proffer any evidence of a conspiracy apart

from the allegations regarding NECC's agreement with the Saint Thomas health care provider defendants to provide fake names to fulfill a regulatory requirement and a "conclusory statement that 'the clinic related defendants had similar communications with NECC.'" *Id.* These new factual arguments warrant a brief response in view of the Premier Defendants' recent discovery responses referred to in their Reply brief.

Premier's own responses actually shows that, in remarkably similar fashion and manner to the Tennessee health care providers, false and fraudulent prescription orders were regularly submitted by the Premier Defendants to NECC as part of concerted scheme to circumvent the Massachusetts requirement that compounded medications be dispensed only in response to patient specific prescriptions; requirements that were designed to protect patients and the public from unsafe drug dispensing and distribution practices. As described and documented in the annexed declaration of Michael Coren, Esq. ("*Coren Declaration*"), the Premier Defendants' recent discovery responses show that Premier personnel listed previously treated and not upcoming patient names on NECC's prescription order forms in order to obtain and maintain office inventories of NECC's compounded preservative-free methylprednisolone acetate for future patients. This conduct, established by Premiers' own prescription records, is illegal under Massachusetts pharmacy law.<sup>1</sup>

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<sup>1</sup> See, 105 CMR § 700.12. In addition, the use of past patient names by a healthcare practitioner to obtain prescription medication to be used on other patients or by a pharmacy to dispense office supplies of a compounded controlled substance violated New Jersey's administrative regulations that require prescriptions and prescription labels relate to specific patients. N.J.A.C. 13:39-7.12(requiring patient name as part of labeling); N.J.A.C. 13:39-11.21 (Same); N.J.A.C. 13:35-7.2 (requiring a prescription to contain the patients full name, address and age. It also violates a patient's privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) by disclosing patient names to another person (NECC) for purposes of other than the patients' treatment or care or billing for services. 42 U.S.C.A. § 1320d-6 ("A person who knowingly and in violation of this part . . . discloses individually identifiable health information to another person . . . shall be punished."))

The compounded preservative-free MPA obtained in this manner was then subsequently passed off to future Premier patients and their insurance carriers (or to Medicare or Medicaid) as brand name “Depo-Medrol.”<sup>2</sup>

Here, the facts in the Complaint are sufficient to make out conspiracy and other claims or, if found not to be, clearly can be made so by amendment in light of Premier Defendants’ recent discovery responses as described in the annexed *Coren Declaration*. The Master Complaint alleges that Premier<sup>3</sup> was required under Massachusetts law to write and submit prescriptions for patients it intended to administer NECC’s MPA during procedures, and both NECC and the Premier defendants knew that NECC under governing Massachusetts law could only legally dispense compounded medications in response to patient-specific prescriptions. Because Premier could not provide NECC with such patient lists, the Complaint alleges that NECC suggested Premier submit list of *any* names, such as past patients, and based on that would dispense the amounts of drugs requested on Premier’s purchase orders.

The Complaint goes on to allege that Premier complied and became part of NECC’s fraudulent and illegal scheme by submitting lists of former patients regardless of whether those patients would actually be administered NECC’s MPA (or other NECC drugs) that were being dispensed pursuant to NECC’s prescription order forms. The Complaint also alleges that

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<sup>2</sup> NECC’s preservative free MPA is not “Depo-Medrol,” which is a brand name medication. Nor is it a “generic” version of Depo-medrol. Both brand name Depo-medrol and FDA approved generic versions are manufactured (not compounded) medications produced and packaged in tightly controlled FDA approved and inspected facilities. Additionally, Depo-Medrol and its approved generics contain a preservative ingredient that NECC’s compounded preservative free knock-off version did not.

<sup>3</sup> The Master Complaint lists a number of facilities that received recalled lots of MPA from NECC. Those hospitals, clinics, healthcare facilities, and their physicians, staff, agents, and employees are referred to in the Master Complaint collectively as the “Clinic Related Defendants.” Compl. ¶¶ 22-23. The Premier Defendants are included in this defined term.

Premier knew or should have known that patient-specific names were required but instead ordered NECC pharmaceuticals in bulk using previously treated patients' names in furtherance of NECC's scheme to circumvent Massachusetts' law and make sales. The Complaint goes on to provide specific examples of one of the Clinic Related Defendants, Saint Thomas Neurosurgical and states that Premier had similar communications with NECC (*See*, Master Complaint ¶¶ 339-351). These allegations and others are sufficient to make out a *prima facie* case of conspiracy.

As the *Coren Declaration* makes clear, the PSC is able to amend the Complaint to allege facts establishing the Premier Defendants complicity in the scheme and conspiracy to circumvent Massachusetts laws and regulations. The PSC's opposition to Premier's Motion to Dismiss asked in the alternative for leave to amend the Master Complaint to add additional facts along the lines of those now presented in the *Coren Declaration*. These facts are drawn from materials produced by Premier after the Master Complaint was filed.

**WHEREFORE**, Plaintiffs respectfully request that the Premier Defendants' motion to dismiss be denied or, alternatively, be given opportunity and leave to amend to cure any pleading deficiencies found by the Court.

Dated: April 23, 2014

Respectfully submitted,

/s/ Michael F. Barrett

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**CERTIFICATE OF SERVICE**

I, Michael F. Barrett, hereby certify that I caused a copy of the above Plaintiffs' Steering Committee's Sur-Reply Relating to Premier Defendants' Motion to Dismiss Pursuant to F.R.C.P. 12(b)(6) to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

**Dated: April 23, 2014**

/s/ Michael F. Barrett  
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